Organ and Tissue Donation Services in Hospitals

Guidelines

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REPORT OF THE SUB-COMMITTEE
ON INSTITUTIONAL PROGRAMS

GUIDELINES FOR ESTABLISHING STANDARDS
FOR SPECIAL SERVICES IN HOSPITALS

ORGAN AND TISSUE DONATION SERVICES IN HOSPITALS

Health Services Directorate
Health Services and Promotion Branch

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NOTE

The information contained in these guidelines is considered current as of November, 1986; however, since many aspects of health care and health technology are constantly changing, we welcome any suggested amendments. Information on new developments or related issues should be directed to:

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Further copies of these guidelines, in English and in French, can be obtained from the above address.

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PREFACE

Technological advancement and changes in the delivery of health care services have led to the need for guidelines to assist in planning and implementing institutional programs and services. The guidelines[1] that follow represent one of a series of publications produced under the direction of the Subcommittee on Institutional Program Guidelines. They provide a consistent definition of requirements for a number of special care units, services, and programs in health institutions.

In general, guidelines are based on information, knowledge, experience, research, and expert opinion from health professionals and organizations throughout Canada. Additional material is often obtained from national and international health organizations and from other experts knowledgeable in the subject matter. By this method, many Canadians from across the country have contributed to the guidelines and a consensus on the suggested approach has been achieved.

Background

Under the direction of the Federal/Provincial Advisory Committee on Institutional and Medical Services, the guidelines program has been in operation since 1972. A standing subcommittee of the Advisory Committee, the Subcommittee on Institutional Program Guidelines, composed of federal and provincial government and professional representatives, coordinates the development of the guidelines commissioned by the Advisory Committee.

The guidelines are produced by expert working groups of health professionals, some of whom are

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[1] A complete list of Institutional Program Guidelines appears in Annex XI.

government representatives. The final draft is reviewed and recommended by the Subcommittee for approval by the Advisory Committee.

Purpose

The purpose of the guidelines is to provide a comprehensive definition of requirements for services in health institutions. While a consensus of expert knowledge and experience is reflected in the guidelines, they should not be regarded as rigid standards. Provincial health authorities may modify the application of guidelines to meet their needs.

Where development of a service is being contemplated, we believe the guidelines will be of help in determining the need for such a service either locally, regionally, or in some cases provincially or interprovincially.

Established services may take advantage of the guidelines in screening deficiencies and solving problems without the need to develop new services. Where a service already exists the guidelines will help:

- to identify problems related to administration, personnel, equipment and facilities;

- to determine necessary remedial action;

- to set priorities for corrective measures on the basis of clinical need, funding and the degree to which the service is deficient.

Future

The dramatic increase in the number of intensive and special care services in health institutions has given rise to the need for additional facilities, specialized equipment and highly-trained personnel. At the same time, new approaches to patient care have evolved in a manner that emphasize the need for a continuum of care in which admission to an institution is only one aspect of total care. Therefore,

linkages along the health care continuum, ranging from illness prevention to chronic care, must be identified. As new treatments and procedures are put into practice, there will be a continuing need for guidelines to assist those involved in the planning and operation of institutional services.

Revisions

Due to the rapidly changing nature of health care delivery, guidelines will need updating and revision. The Subcommittee on Institutional Program Guidelines plans and oversees these revisions.

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ORGAN AND TISSUE DONATION SERVICES IN HOSPITALS

PREAMBLE

Organ and tissue transplantation, being adopted increasingly as a treatment for individuals with certain end-stage diseases, provides them an opportunity for an improved quality of life or for a second chance at life.

There are two sources of transplantable organs and tissues: the living donor in the case of paired organs or regenerative tissue, and the cadaveric donor.

Recent advances in surgical and medical techniques and in organ and tissue preservation and the introduction of cyclosporine, an immunosuppressive drug, have led to a dramatic increase in the number of transplantation procedures. To-day, hundreds of Canadians are on waiting lists. Many will not be treated by transplantation because of the lack of organs and tissues. Studies indicate that only about 12%[1] of potential cadaveric organ donors become actual donors. If only 50% of them were to become donors there could be more than sufficient organs.[2]

A significant impediment to organ and tissue retrieval is the lack of established systems in hospitals for identifying and referring potential donors.

The purpose of these guidelines is to provide hospitals with direction for planning and organizing cadaveric organ and tissue donation services where they do not exist now and for developing further

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1. Stiller, Calvin, and Neil McKenzie. "A Plea For The Heart, The Kidney, The Liver, The ... ", Medical Post, February 5, 1985, p. 12.

2. Gilmore, Ann, "Producing Donor Organs: Firm but friendly encouragement required", Canadian Medical Association Journal, Vol. 134, April 15, 1986, p. 932.

existing programs. Donations by living persons are not dealt with in this document. Hospitals wishing to learn more about donations by living persons are encouraged to contact the regional transplant program. National guidelines for such donations have yet to be developed.

It is important to distinguish perfusible organs (e.g. kidney, liver, heart, heart/lung, lung and pancreas) from non-perfusible organs and tissues (e.g. eyes, skin, bone, heart valves, dura mater, fascia)[3]. Donors of perfusible organs are usually relatively young and previously healthy individuals who have suffered from a major accident or medical catastrophe resulting in the fatal interruption of brain function. These donors must be maintained after death on a donor support system[4] to ensure ventilation of the lungs and adequate blood flow to organs until they are removed for transplantation. Donors of non-perfusible organs and tissues, referred to hereafter as "tissues", do not require the maintenance of blood flow after death.

Guidelines for providing transplant services are not discussed in this document. Hospitals interested in learning about these services should refer to the Guidelines for Vital Organ Transplant Centres, 1986.

As the criteria for donor selection widen and preservation techniques improve, the potential number of usable organs and tissues will increase. However, expanded criteria for recipient selection, increased recognition of transplantation as an accepted treatment modality and more indications for transplanta-

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3. Heart valves, dura mater and fascia are not retrieved routinely and will not be discussed in this document. Information on these tissues is available from regional transplant programs.

4. The donor support system includes that equipment used to artificially maintain the respiration and blood circulation of a brain dead donor. (Commonly known as an "artificial life support system").

tion will result in the earlier referral of more patients. The chronic shortfall of organs and tissues for transplantation could intensify.

The organ and tissue donation system in Canada is essentially one of "encouraged voluntarism". Provincial laws covering donation, most modeled on the Uniform Human Tissue Gift Act, prescribe a donation system based on explicit consent. That is, with some exceptions (see Annex V - Legal Considerations), a physician may not remove organs or tissues for transplantation without the consent of the donor or other specified persons. Even if consent has been given by the donor before death, it is the practice to request the consent[5] of the donor's family.

Organ transplantation depends on the altruistic nature of people to help their fellow humans. Donation provides the donor family with a means to assist others and also to alleviate its grief in the loss of a loved one.

Organs and tissues obtained in one hospital are commonly transplanted in other hospitals, sometimes outside the province or country. Several organs and tissues may be retrieved from one donor. Effective and efficient mechanisms are essential if potential donors are to be identified and organs and tissues retrieved in a timely fashion and transported to places where they can be used optimally.

Organ and tissue donation is facilitated by a nationwide network of persons entitled "transplant coordinators" who most commonly are situated in regional transplant centres. Eye donation, in most cases, is arranged by coordinators of regional or provincial

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5. When a donor has indicated the wish to donate prior to death, the family is approached for endorsement of that wish. For a further explanation, see page 33 - "Approaching the Family About Donation".

eye banks. A list of provincial and regional organ and tissue retrieval programs in Canada is provided in Annex I.

To ensure the maximal degree of collaboration it is necessary for the roles and interactions of groups and individuals involved in organ and tissue donation to be clearly defined and understood by all concerned.

Although there is no formal arrangement for coordination among agencies, nationwide coordination of organ and tissue donation and exchange is effected through (i) close working links among coordinators made possible by twenty-four hour telephone contact; (ii) a computer network covering most Canadian transplant centres; (iii) linkages with other North American computer networks; and (iv) regular national meetings and exchanges of information.

In addition to assisting hospitals in developing donation programs these guidelines will aid in the further development of a system for organ and tissue donation and exchange in Canada.

Not all hospitals have specialized units to undertake transplantation procedures or to maintain donors on support systems until organs are removed. However, all hospitals can participate in the donation process, at least for eyes. Optimal retrieval of organs and tissues requires that each hospital adopt a systematic approach based on written policies and procedures in accordance with its resources and medical and administrative policies and those of its funding agencies.

SECTION A - THE DONATION PROCESS - SEQUENCE OF EVENTS

1. Perfusible Organs

Figure I illustrates the sequence of major events in the donation process for perfusible organs. A sample checklist of the significant activities involved in each step is provided in Annex II. A number of variables affects both the sequence of events and the extent to which a hospital may be involved. Primary among these are the availability of the organization and human and physical resources required to carry out each step. A classification of hospitals by resources required is provided in Item 3 below. Many of the steps may occur simultaneously or in a different order depending on the situation. The need for coordination is intensified in the case of multi-organ donations.[6] Hospital staff should be flexible and have the ability and authority to respond to unusual circumstances.

The organizational, staff and physical resource requirements for the donation of perfusible organs are discussed in Section B, "The Donation Process - Administrative and Organizational Considerations", pages 11-27. Details of each step are outlined in Section C, "The Donation Process - The Key Elements", pages 28-41.

Hospitals involved in the donation of perfusible organs can and should participate also in the donation of tissues.

2. Tissues

Figure II illustrates the donation process for tissues. Heart beat and respiration are not requisites for tissue donors. Therefore, these donors may be patients dead on arrival at the hospital or who have died in hospital. The organization, human and

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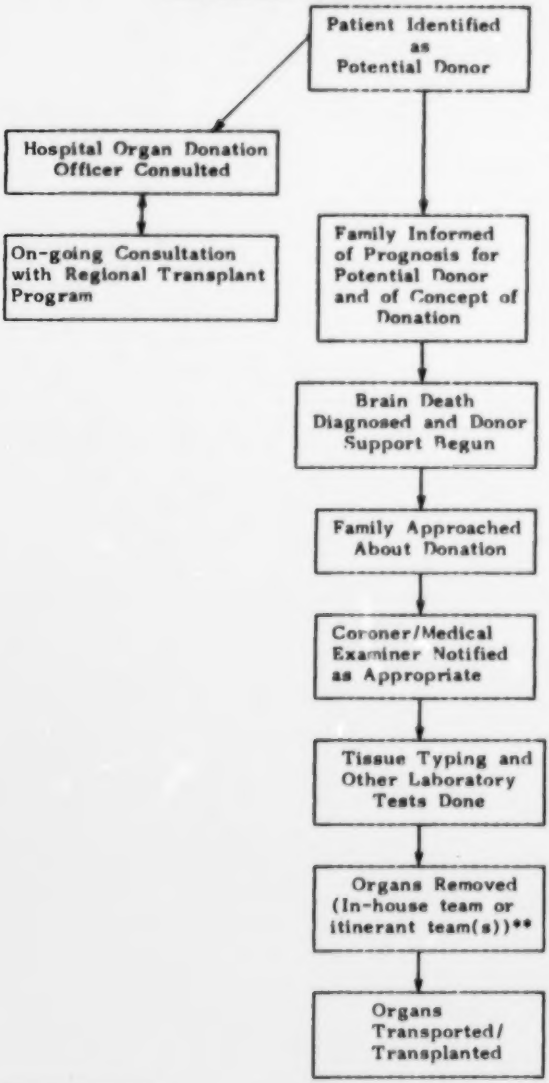
6. Multi-organ donation involves the removal of more than one organ or tissue from a cadaveric donor.

FIGURE I
THE DONATION PROCESS
PERFUSIBLE ORGANS*

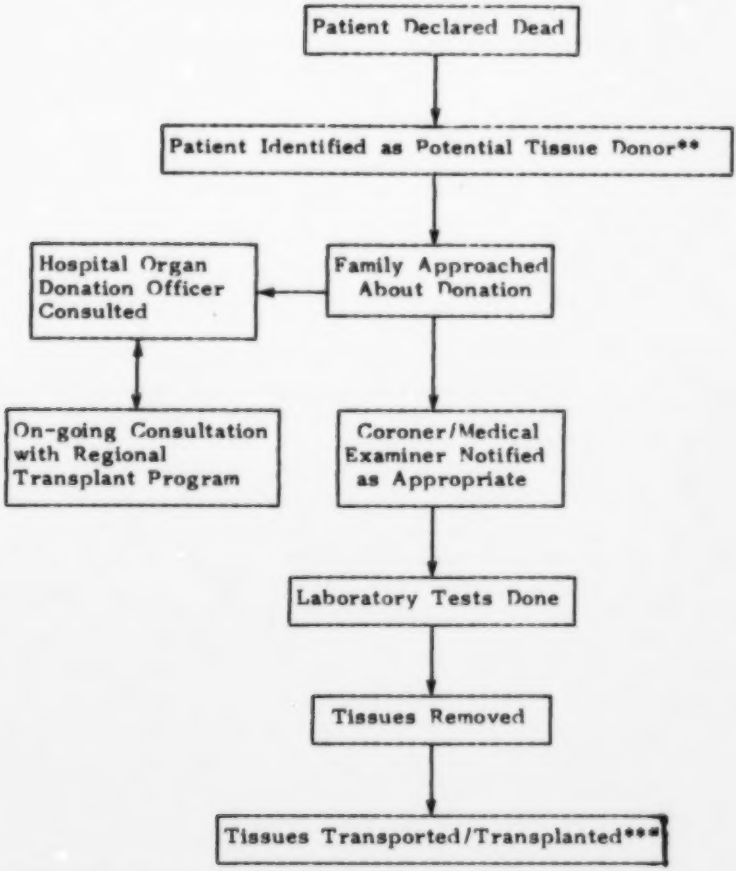

Patient Identified as Potential Donor
Hospital Organ Donation Officer Consulted
On-going Consultation with Regional Transplant Program
Family Informed of Prognosis for Potential Donor and of Concept of Donation
Brain Death Diagnosed and Donor Support Begun
Family Approached About Donation
Coroner/Medical Examiner Notified as Appropriate
Tissue Typing and Other Laboratory Tests Done
Organs Removed (In-house team or itinerant team(s))**
Organs Transported/ Transplanted

* Tissues such as eyes, bone and skin can also be provided by donors of perfusible organs.

** Heart/lung and lung donors are usually transported to the recipient transplant centre for organ removal while pancreas donors must be transported there for organ removal.

FIGURE II

THE DONATION PROCESS
TISSUES*


Patient Declared Dead
Patient Identified as Potential Tissue Donor**
Hospital Organ Donation Officer Consulted
Family Approached About Donation
On-going Consultation with Regional Transplant Program
Coroner/Medical Examiner Notified as Appropriate
Laboratory Tests Done
Tissues Removed
Tissues Transported/Transplanted***

* This refers to situations where tissues only are donated.

** The patient may also be identified before death as a potential donor.

*** Removal of bones and skin is limited usually to hospitals within the same metropolitan area as the facility(ies) doing the transplant of these tissues.

physical resources and medical and other professional considerations required for the tissue donation process are included in the discussion of perfusible organs.

3. Classification of Hospitals by Resources Required to Participate in the Donation Process

The following classification is based on the fact that every hospital can participate in the donation process, at least for eyes. A hospital should be able to identify itself in one of the four following categories:

(1) Hospitals Only Able To Identify Potential Organ Donors And Refer Them To Secondary Or Tertiary Care Centres

These are usually small to medium sized hospitals with limited medical, nursing and other resources for critical care. Some larger hospitals which choose to refer brain damaged patients can also be included in this category. Hospitals which ordinarily refer brain damaged patients for assessment and treatment elsewhere may, on occasion, retain them because of the apparent futility of aggressive treatment. Such persons should be considered as possible organ donors and, if appropriate, referred with this in mind.

Not all hospitals in this category will have the capacity to maintain respiration and circulation for the sustained periods required for the diagnosis of brain death and donor support. All should, however, be familiar with the donation criteria and have protocols for stabilizing potential donors and transferring them to appropriate centres.

Where a patient being transferred has a low probability of survival, the family should be informed about the possible opportunity for organ donation. The potential for donation and the family's views should be communicated to the receiving centre.

If the patient is dead on arrival or is clearly not a suitable donor of perfusible organs, these hospitals

should undertake on site tissue donation where appropriate.

(2) Hospitals Able To Diagnose Brain Death And Support Donors Until The Arrival Of Itinerant Retrieval Teams Or Transfer To Organ Retrieval Hospitals Or Transplant Centres

These hospitals have the capacity to maintain respiration and circulation for the sustained periods required for the diagnosis of brain death and for donor support. Some of these hospitals may undertake to diagnose brain death, support donors, approach families about donation and provide medical and nursing staff and operating room facilities to assist itinerant teams in organ removal. Other hospitals, especially those in close proximity to a transplant centre, may - with the prior agreement of the centre and donor families - not undertake extended donor support or organ removal, but transfer these persons immediately to the transplant centre.

(3) Hospitals Able to Remove Organs and Tissues

In addition to the capability to diagnose brain death or confirm it in donors transferred from other hospitals and to support donors, such hospitals have the resources to remove and preserve organs for transportation to a transplant centre. This is usually limited to kidney donation and requires a general surgeon or urologist and general nursing staff experienced in kidney removal for transplantation. For heart or liver donations, the donors are referred to transplant centres or itinerant retrieval teams come to donor hospitals with assistance being provided by hospital staff. For heart-lung and lung donations, donors are commonly transferred to transplant centres. Pancreas donors must be transferred to the receiving transplant centre for organ removal.

These hospitals may be able to perform eye, skin, bone or other tissue transplants, but are not designated as perfusible organ transplant centres. Usually, bone and skin removal are done in hospitals

within the same metropolitan area as the facility(ies) performing the transplants of these tissues.

(4) Hospitals Able to Remove and Transplant Organs and Tissues

In addition to being able to perform the activities described in Categories 1-3, a small number of hospitals in Canada have the specialized staff and equipment to transplant one or more organs and probably several types of tissues. Such hospitals also can provide staff to assist itinerant retrieval teams to remove organs for transplantation elsewhere.

SECTION B - THE DONATION PROCESS - ADMINISTRATIVE AND ORGANIZATIONAL CONSIDERATIONS

PART I - GENERAL CONSIDERATIONS COMMON TO ALL HOSPITALS

1. Deciding on Involvement

It is important for hospitals starting donation programs to determine their level of involvement and the corresponding resource requirements. Hospitals should contact regional transplant programs[7] for assistance in the assessment process. This liaison will help minimize duplication, enhance uniformity of procedures and ensure coordination of activities.

Hospitals may find it useful to form a special committee or to designate an individual to (i) perform a review of past deaths to estimate the number and types of potential organ and tissue donors, and (ii) assess their resources and those of their communities. A committee should include medical, nursing and management staff. The individual should consult appropriate medical, nursing and management staff.

Assessing Resources

Matters to be considered are:

- human and physical resources needed to (i) identify potential donors; (ii) diagnose brain death; (iii) support or transport donors; and (iv) remove and transport the organs and tissues;

- opportunities for and implications of linkages with regional transplant programs;

- annual costs of the program (e.g. start-up and on-going program costs);

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7. "Transplant programs" include perfusible organ and eye transplant programs.

- hospital practices which promote or discourage donation.

Estimating The Number and Types of Potential Donors

The committee or designated individual should perform a one year retrospective review of all hospital deaths up to age 70, including newborns. This review must include deaths in critical care or emergency units. Patients are identified who have died of conditions that would permit organ and/or tissue donation. (See Donor Assessment, page 32). The quality of medical care prior to or at the time of death need not be considered. Measures to protect the identity of deceased persons must be followed.

The review of deaths should identify:

- size of the potential donor pool;
- age distribution of potential donors;
- seasonal distribution of potential donations;
- distribution of diagnoses compatible with donation;
- length of hospital stay of potential donors prior to death;
- care area in which such deaths occurred;
- specific organs and tissues potentially available for donation.

The findings and recommendations should be reported to hospital management and medical staff and then, if appropriate, to the board of trustees for a final decision.

2. Program Development and Implementation

Organ Donation Committee

Following a decision to participate, a hospital can, depending on resources and intended program size, establish an Organ Donation Committee (O.D.C.) or designate an individual to develop, implement and monitor the program. The O.D.C. should comprise those individuals most likely to participate, e.g. medical, nursing, social work, chaplaincy and admin-

istrative staff, and, where appropriate, should consult the hospital solicitor. **This activity should include representatives of regional transplant programs if possible.**

Policies and Procedures

The O.D.C. or designated individual should develop policies and procedures tailored to the hospital's involvement and circumstances and consistent with those of regional transplant programs. These should cover:

- o donor identification - including a system to ensure that all potential donors are identified and formal assessments of their suitability made and recorded according to the criteria for each type of organ/tissue. Hospitals might consider a system of recorded consideration;[8] (See also Approaching the Family About Donation, page 33 and Annex X);
- o diagnosis of brain death - including criteria for the diagnosis and physicians authorized to diagnose brain death;
- o approaching families about donation - including staff involved and procedures to be followed;
- o liaison with the regional transplant programs - including arrangements to ensure the timely retrieval and optimal disposition of transplantable organs and tissues. The respective responsibilities of the hospital and regional programs and matters requiring coordinated action should be delineated;

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8. In such a system, the physician records on the hospital chart of each deceased patient (i) that the patient was assessed as a potential donor; (ii) whether the patient met the donor criteria; (iii) whether the family was approached about donation; and (iv) the family's decision. If donation is not discussed with the family, the reasons are given. The hospital audits charts of deceased patients to assess the system's performance in organ and tissue donation. See Annex X for a sample form.

- notification of the coroner/medical examiner - outlining the circumstances requiring notification and obtaining and recording consent of the coroner/medical examiner to donation and/or autopsy;

- tissue typing and other laboratory tests - including sending of samples to a tissue typing laboratory (in-house or other designated laboratory) and notifying regional transplant programs of test results;

- donor support - perfusible organs - including (i) procedures for alerting and involving staff on a 24 hour basis; (ii) transportation of donor bodies to transplant centres; and (iii) methods for support;

- removal of organs and tissues - including (i) procedures and staff involved for each organ and tissue; (ii) booking surgery; (iii) arrangements for the arrival and departure of itinerant retrieval teams and the granting of temporary hospital privileges to them and (iv) documentation of death, family endorsement/consent and consent of the coroner/medical examiner on the donor's hospital chart prior to organ removal;

- care and transportation of donor organs and tissues - including preservation techniques specific to each organ and tissue and transportation arrangements (and costs if any) to designated transplant centres or, in the case of eyes, to the regional eye bank.

A list of items for inclusion in a policy/procedures manual is included in Annex III.

3. Program Evaluation and Quality Assurance

Program evaluation and quality assurance address similar issues: what standards pertain to the donation process and how well the program fulfills those criteria. Quality assurance relates to the quality of services provided, while program evaluation pertains to an overall perspective of the program. Details on

the nature of and methods for quality assurance and program evaluation, e.g. conducting an audit, are provided in Annex IV.

Program evaluation and quality assurance should be the responsibility of the O.D.C. or designated individual. Persons involved will vary with the size of the hospital and its donation program. The assistance of health record personnel and sufficient resources to gather information requested by regional transplant programs are needed.

4. Public Education/Community Liaison

An integral part of a donation program is a dynamic and multifaceted public education program. Families unfamiliar with the concept of donation are less able to deal with it when a loved one dies.

Hospitals may be asked for information by local media and community groups. Hospitals wishing to initiate community education programs, e.g. speaking engagements, mall displays or contact with the media, may obtain information materials from regional transplant programs. Any hospital may place donor information, e.g. donor cards and brochures, in the hospital lobby.

An educational program is achievable at minimal cost. Trained volunteers may assist. Generally, the details and complexity of the program will be determined by the time available and the interest of those giving and receiving the information.

5. Staff Training and Qualifications

Staff involved should have appropriate background and training. Most importantly, staff must be committed to organ donation and transplantation. Understanding the donation process is a key to their participation.

In-Service Education Program

This program should include basic information on the state-of-the-art in organ donation and transplantation including types of organs retrieved, benefits of donation for donor families and transplant recipients, professional responsibility to participate in the donation process and related ethical and legal issues.

Information on donation should be a regular part of the in-service program for critical care and emergency staff and made available to all others including house staff and student nurses. Experience in the donation process should be part of their training.

In-service education programs should be delivered with the assistance of regional transplant programs and in consultation with heads of departments involved. Guest lecturers at grand rounds, workshops and seminars should be considered and information made available in the hospital medical library.

An important ingredient in education programs is feedback to staff involved in donations. Where possible, opportunities for staff of donor hospitals to meet or communicate in writing with transplant recipients should be provided.

Continuing Education

Transplant medicine is a rapidly changing specialty. In establishing program budgets consideration should be given to the staff's attending appropriate educational workshops, seminars and conferences and visiting other donation and transplant programs. Staff should also participate in the evaluation of donation programs and in research activities related to the donation process.

6. Legal Considerations

All provinces have legislation governing donation and transplantation. Most of them have modeled the legislation on the Uniform Human Tissue Gift Act. A copy of the Act and discussion of its applications

and other legal considerations are included in Annex V. Hospitals should obtain and review a copy of their relevant legislation when developing policies and procedures.

7. Religious Considerations

Three major faiths - Jewish, Roman Catholic and Protestant - recognize the moral and ethical justification, medical need and legal basis for organ and tissue donation and transplantation. Some faiths, such as Jehovah's Witnesses, have no official position on donation, leaving the individual to make a personal decision. The views of families belonging to faiths which do not endorse donation must be respected. Hospitals must decide whether or not these families should be offered the opportunity to donate.

PART II - RESOURCE REQUIREMENTS BY CLASSIFICATION OF HOSPITAL

The manpower and physical resources required depend on a hospital's level of involvement in the donation process, the number of potential donors and help available from regional transplant programs. For some hospitals, the need for new resources will be minimal.

Common to all hospitals is the requirement for medical and nursing staff aware of the need for donors, the benefits of transplantation, donor criteria, the concept of brain death and methods of donor support. It is especially important for medical and nursing staff in emergency and critical care areas of the hospital to be able to identify and refer potential donors.

As described in Part I, the following recommendations are based on the fact that every hospital can be a donor hospital, at least for eyes.

(1) HOSPITALS ONLY ABLE TO IDENTIFY POTENTIAL ORGAN DONORS AND REFER THEM TO SECONDARY OR TERTIARY CARE CENTRES

1.1 Staff Establishment And Coverage

Medical and Nursing Staff

Medical and nursing staff required are:

- physicians aware of the criteria for brain death. For medicolegal reasons it may be desirable for brain death to be recognized as soon as possible. This can be done in any hospital and, if necessary, confirmed in the receiving centre;

- a general practitioner, ophthalmologist or pathologist for eye removal (enucleation). In some provinces, a technician from the regional eye bank may be available to assist in or carry out this procedure;

- physicians and nurses familiar with basic donor stabilization and support pending and during transfer to secondary or tertiary care centres.

Hospital Organ Donation Officer

An organ donation officer may be designated to coordinate donations, program and policy development, staff and public education and liaison with the regional transplant programs.

In smaller community hospitals, the officer may be a registered nurse who has other duties. The officer's day-to-day involvement may be minimal depending on the number of potential donors.

A job description outlining the functions and responsibilities of the officer should be written in consultation with regional transplant programs. A list of responsibilities this person may perform is found in Annex VI.

Social Services [9]

Responsibilities may include counselling donor families and consultation with staff about the feelings and needs of donor families. This service may be provided by a nurse or other staff member who has established a rapport with the donor family.

Provision should be made for follow-up support for families.

Chaplaincy Services [9]

Chaplaincy staff may counsel families about donation as well as provide support to staff. The help of the family's spiritual advisor or of other clergy may be enlisted.

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9. Hospitals in this category may not have social services or chaplaincy services. Assistance may be sought in the community.

Clerical and Other Services

Clerical and typing services are required to maintain records, collect data and perform related duties. These services may be minimal depending on the number of donor referrals and could be provided by staff from other programs.

1.2 Staff Training And Qualifications

An in-service education program should be conducted in conjunction with regional transplant programs to inform staff about organ and tissue donation and transplantation and train them in donor identification, and referral, basic donor support and methods for approaching families about donation.

1.3 Supporting Departments and Services

Admitting (for notification of signed driver's licence or donor cards);
Health Records (for audit process);
Volunteer Services (for public education programs).

1.4 Space Allocation And Utilization

Family Quiet Room

A room should be designated for donor families to be alone and to meet with hospital staff. This room should provide privacy and be situated close to the patient care area to facilitate access to staff.

Office Space

The amount and type of office space will depend on the donation program. Space may be required to maintain files and communicate privately face-to-face and by telephone.

1.5 Equipment

Equipment suggested is that required to assess brain stem reflexes, support donors prior to transfer and remove eyes.[10]

(2) HOSPITALS ABLE TO DIAGNOSE BRAIN DEATH AND SUPPORT DONORS UNTIL THE ARRIVAL OF ITINERANT RETRIEVAL TEAMS OR TRANSFER TO ORGAN RETRIEVAL HOSPITALS OR TRANSPLANT CENTRES.

2.1 Staff Establishment and Coverage

Medical and Nursing Staff

In addition to the requirements provided in Item 1.1 (page 18), there must be available:

- physicians trained in the diagnosis of brain death;
- a physician (e.g. anaesthetist, nephrologist, urologist, internist or surgeon) for donor assessment and hemodynamic and pharmacological management;
- nurses familiar with donor support protocols. (Donors on support systems require individual nursing care in a critical care environment);
- medical and nursing staff able to assist itinerant organ removal teams where appropriate.

Where possible, and if desired by staff, different staff should assume the care of patients after brain death has been declared and donor support begun. Medical and nursing staff trained in donor support should be available on a 24 hour basis.

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10. Equipment required for eye removal includes an enucleation tray, preservation solutions and a special transport container available from the regional eye bank.

Hospital Organ Donation Officer

See Item 1.1 (page 19).

Social Services

See Item 1.1 (page 19).

Staff trained in crisis intervention and in dealing with bereaved families may be available.

Chaplaincy Services

See Item 1.1 (page 19).

Clerical and Other Services

See Item 1.1 (page 20).

Technical Support

When itinerant retrieval teams do not include a perfusion technician a staff member trained in organ perfusion and storage will be required.

2.2 Staff Training and Qualifications

In addition to the points in Item 1.2 (page 20) staff should receive training and on-going education in advanced donor support.

2.3 Supporting Departments and Services

In addition to those departments listed in Item 1.3 (page 20) there must be:

Laboratory Services

A laboratory is needed to perform hematological tests normally required to care for critically ill patients as well as tests to evaluate donated organs and tissues. Tests and protocols should be determined by regional transplant programs.

2.4 Space Allocation and Utilization

See Item 1.4 (page 20).

2.5 Equipment

See Item 1.5 (page 21).

Standard neurological instruments are used to diagnose brain death.

Equipment to support donors until removal of organs is the same as that required to care for critically ill patients, i.e., to:

- monitor cardiovascular, pulmonary, fluid balance and electrolyte changes;
- determine radiological changes;
- perform colloid infusion, blood transfusion, and percutaneous insertion of central venous and arterial catheters.

(3) HOSPITALS ABLE TO REMOVE ORGANS AND TISSUES

3.1 Staff Establishment and Coverage

Medical and Nursing Staff

In addition to the requirements listed in Items 1.1 (page 18) and 2.1 (page 21) there must be:

- an anaesthetist for hemodynamic and pharmacological management intra-operatively;

- specialists in fields such as infectious disease, gastroenterology, cardiology, radiology, pulmonary medicine and urology;

- surgeons to remove specific organs. Kidneys are commonly retrieved by staff urologists or general surgeons experienced in the removal of kidneys for transplantation. In most cases of heart and liver donation, retrieval teams will come from transplant centres;

- nursing staff trained in organ and tissue donation.

Hospital Organ Donation Officer

See Item 1.1 (page 19)

The complexity of this officer's role will increase in cases of multi-organ donation and where more than one transplant centre is involved in the retrieval.

Social Services

See Item 1.1 (page 19) and 2.1 (page 22).

Some dedicated hours from social workers will be required.

Chaplaincy Services

See Item 1.1 (page 19).

Clerical and Other Services

See Item 1.1 (page 19).

Technical Support

A perfusionist or other suitably trained individual will be required. (See also Item 2.1 page 22).

3.2 Staff Training and Qualifications

In addition to the requirements in Items 1.2 (page 20) and 2.2 (page 22) staff should be trained and maintain skills in state-of-the-act organ removal and preservation techniques.

3.3 Supporting Departments and Services

See Items 1.3 (page 20) and 2.3 (page 22).

3.4 Space Allocation and Utilization

See Item 1.4 (page 20).

3.5 Equipment

In addition to the requirements in Items 1.5 (page 21) and 2.5 (page 23) there must be the following facilities and equipment:

- an operating room equipped with instruments for major surgical procedures;

- solutions and equipment for perfusion and preservation.

(4) HOSPITALS ABLE TO REMOVE AND TRANSPLANT ORGANS AND TISSUES [11]

4.1 Staff Establishment and Coverage

Medical and Nursing Staff

In addition to the requirements outlined in Items 1.1 (page 18), 2.1 (page 21) and 3.1 (page 23), there must be:

- transplant specialists for specific organs and tissues.

Transplant Coordinator

Those institutions carrying out transplants may wish to broaden the hospital organ donation officer's responsibilities to include involvement in the transplantation of perfusible organs, maintenance of lists of patients waiting for transplantation and provision of guidance and assistance to donor hospitals. In most cases the transplant coordinator is also the regional or provincial transplant coordinator. A sample job description for a regional transplant coordinator is provided in Annex VII[12].

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11. See also Guidelines for Vital Organ Transplant Centres, 1986.
12. Ibid.

The waiting list for eye transplantation is kept by the regional or provincial eye bank coordinator. This coordinator's duties are similar to those of the transplant coordinator (See Annex VII) but do not include participation in the removal of eyes.

The regional transplant coordinator should have at least one year's experience in such work and the administrative skills for program management and data collection and analysis. The coordinator should be prepared to work on an on-call basis and be available to travel to donor centres if necessary.

Social Services

See Item 1.1 (page 19), 2.1 (page 22), 3.1 (page 24).

Chaplaincy Services

See Item 1.1 (page 19).

Clerical and Other Services

Regional transplant coordinators will require secretarial support including assistance to:

- send letters of thanks to medical and nursing staff of donor hospitals and to donor families;
- correspond with other transplant centres and with health insurance programs (regarding medical fees and charges, etc.);
- maintain records;
- provide information on request.

4.2 Staff Training and Qualifications

In addition to the requirements of 1.2 (page 20), 2.2 (page 22) and 3.2 (page 24) staff should be trained and kept up-to-date in transplant procedures.

4.3 Supporting Departments and Services

See Items 1.3 (page 20), 2.3 (page 22) and 3.3 (page 24).

4.4 Space Allocation and Utilization

See Item 1.4 (page 20).

4.5 Equipment

See items 1.5 (page 21), 2.5 (page 23) and 3.5 (page 25).

SECTION C - THE DONATION PROCESS - THE KEY ELEMENTS

This section discusses the major procedures involved in each step in the donation process. As noted in Section A, the sequence of these steps and the individual hospital's capability to carry out each step will vary.

Generally, Category I hospitals should be familiar with steps 1 through 5 and 7.2; Category II hospitals with steps 1 through 7 and Category III & IV hospitals with steps 1 through 8. Again, donor hospitals for perfusible organs are capable also of being donor hospitals for tissues while the converse is not necessarily true.

1. Donor Identification and Referral

1.1 Responsibility for Identification and Referral of Potential Donors

Patients may have indicated a desire to donate by signing the consent portion of the driver's licence or a donor card. Appropriate hospital personnel should contact police and ambulance staff to determine the existence of signed consent or seek it among the personal effects of potential donors. Donation may also be suggested by families of dying patients.

Any health professional can identify potential donors. Staff uncertain about the suitability of potential donors should consult the hospital organ donation officer. If there is no donation officer on staff, regional transplant programs should be contacted.

1.2 Initial Identification

Perfusible organs must be obtained from donors pronounced dead on the basis of neurological evidence but with respiratory and circulatory function maintained. (See next section - Brain Death and Annex VIII - Guidelines for the Diagnosis of Brain Death). Tissues also can be obtained from such

donors as well as from donors in whom respiration and circulation have not been maintained.

Most perfusible organ donors are relatively young victims of a head injury. Other donors include patients who have died from a primary brain tumor or stroke. Hypoxia of the brain (complicating cardiac and respiratory arrest or profound shock), drug intoxication, metabolic disorders, homicide and suicide are additional causes of death among potential donors. (See Annex IX - Criteria for Organ and Tissue Donation.)

Frequently, more than one organ or tissue can be obtained from a single donor. The unsuitability of one organ or tissue for donation does not necessarily exclude consideration of other organs or tissues. (See Annex IX - Criteria for Organ and Tissue Donation). Also, all donations need not satisfy the ideal criteria for selection as the risks of transplanting sub-optimal organs may be less than the risks for a potential recipient of deferring transplantation.

2. Declaration of Death

2.1 Brain Death

Death can be manifested by irreversible cessation of the functions of the brain or of respiration and circulation. Brain death means the clinical absence of brain function defined as profound coma, apnea and the absence of brain-stem reflexes. Brain death signifies the death of the patient but respiratory and circulatory functions can be supported to maintain organs until removal for transplantation. The diagnosis of brain death by neurological criteria is an absolute prerequisite for the donation of perfusible organs.

2.2 Responsibility For The Diagnosis Of Brain Death

Hospitals should be aware of the provincial legislation concerning the diagnosis of brain death in cases of organ donation and transplantation. In all cases

the diagnosis of brain death should be made by, or in consultation with, physicians experienced in the required examinations and familiar with the accepted criteria to establish it. No physician involved in the care of the proposed recipient may take part in diagnosing the death of the donor. No physician who has diagnosed the death of the donor may participate in the transplantation procedures.

2.3 Criteria For The Diagnosis Of Brain Death

Although some cerebral functions cannot be clinically tested, the necessary and sufficient component of brain death is death of the brain-stem, and death of the brain-stem can be diagnosed reliably by accepted clinical procedures. Criteria for the diagnosis of brain death have been defined by a number of international medical jurisdictions. In 1986, based on current medical information and particularly to avoid diagnostic complications and the possible deterioration of body organs from hypoxia during tests for apnea, the Canadian Congress of Neurological Sciences developed criteria for the diagnosis of brain death. These criteria, accepted and promulgated by the Canadian Medical Association, are found in Annex VIII.

Comments in Annex VIII amplify and explain the criteria and describe the tests and procedures to be employed. It should be noted that caution is recommended in applying the clinical criteria for diagnosis of brain death in infants and young children - especially if the criteria have been present for less than three days. Caution is also necessary for adults if there is uncertainty regarding the etiology or irreversibility of cessation of brain function. To delay the declaration of brain death risks loss of a potential donor from intervening cardiac arrest or the deterioration of organs initially suitable for transplantation. In such circumstances, or when a patient's condition precludes application of all clinical criteria, demonstration of the absence of cerebral perfusion (blood flow) by cerebral angiography or isotope brain scanning can be used to confirm the diagnosis of brain death. However, except for

patients with drug intoxication or hypothermia, electrocortical silence on EEG in conjunction with the clinical findings of absent brain-stem function confirms the diagnosis of brain death. An EEG or a series of EEG's is usually unnecessary. Appropriate corroborative tests can also reassure clinicians and family that no treatable condition has been missed and that irreversible death of the brain has occurred.

2.4 Pronouncement Of Brain Death

The diagnosis of brain death is a statement of clinical fact documented by two examining physicians on the patient's chart. Completion of the death certificate is the separate legal responsibility of an attending physician. In cases of brain death the time of death will be recorded as the time brain death is documented by the first physician.

The nature of the injury or illness causing death may require reporting the death to the coroner/medical examiner and obtaining his/her consent for organ removal. Some transplant programs advocate notifying the coroner/medical examiner of all cases involving organ donation. Autopsy examination of the donor's body subsequent to organ removal can be made with the consent of the family or if ordered by the coroner/medical examiner. The medical certificate of death is completed in the usual way by the coroner/medical examiner or, at his/her request, by the doctor pronouncing the patient's death.

The documentation of death and the coroner's consent for donation make it unnecessary for the diagnosis of brain death to be repeated after transfer of the donor body to another hospital. However, if the absence of a second physician in the referring hospital makes it impossible to confirm brain death, the final diagnosis may be made at the receiving hospital.

3. Donor Assessment

3.1 Perfusible Organs

Donors of perfusible organs are persons diagnosed as brain dead in whom artificial respiration and circulation are maintained. Age, weight and height criteria vary with the organ and are provided in Annex IX - Criteria for Organ and Tissue Donation.

Factors which usually preclude donation are:

- continuing sepsis (systemic bacterial, viral or fungal infection untreated or unresponsive to treatment);

- history of infection by hepatitis B or HIV (Acquired Immune Deficiency Syndrome - A.I.D.S.);

- known malignancy, present or past, other than primary brain tumour or cured basal cell tumour of the skin;

- current intravenous drug use;

- severe insulin dependent diabetes;

- severe chronic hypertension;

- disease or injury of the specific organ being considered for donation.

A hospital should obtain from its regional transplant program the specific criteria used by the program.

3.2 Tissues

Generally, patients meeting the following criteria are suitable tissue donors:

- patients dead on arrival or dying in hospital;
- any suitable organ donor;
- cause of death established;
- eyes and skin - any age;
- bone: females aged 16-50; males aged 16-60;

- absence of sepsis, extra-cranial malignancy, hepatitis, auto-immune disease or transmissible disease and, for eyes, absence of chronic central nervous system disease.

A hospital should contact its regional transplant program regarding specific requirements and protocols for all tissues except eyes. For eyes the hospital should contact the regional eye bank. The criteria for eyes, skin, bone and joints and heart valves are listed in Annex IX.

4. APPROACHING THE FAMILY ABOUT DONATION

Donation offers families an opportunity to create something positive from death and helps many to deal with their grief. To deny them this opportunity may remove a way for them to find meaning in their loss.

The availability of evidence of the deceased person's wish to be a donor influences the approach to the family. Evidence of consent may be used to introduce the possibility of donation and obtain the family's consent for carrying out the wish. That is, the family is asked to "endorse" the donor's wish. In the absence of the donor's consent the family's "consent" is sought. It is appropriate to begin the discussion by asking family members if they had ever discussed donation with the donor.

Legislation does not require family consent if the donor has indicated his/her wish prior to death. However, in most cases, signed consent for family donation is obtained from the family. If the family is not present, consent may be given by telegraphic, recorded telephonic or other recorded message from the family. Unless the donor has indicated the wish to donate a specific organ or tissue only, the concept of multi-organ donation should be discussed.

Evidence of the family consent must be placed on the donor's chart. In those hospitals with a policy of recorded consideration, a form reporting whether the decedent was a potential donor, whether the family was approached, and their decision should be placed on every deceased person's chart. A sample form for such recording is included in Annex X. This form should be completed by the physician when death of the patient is declared. Alternatively, appropriate headings may be included in an existing form completed at the time of death. This will help to remind staff to consider organ donation for suitable patients in the future.

4.1 Responsibility for Approaching the Family About Donation

In most cases the physician decides who should approach the family about donation. Often, this can be a shared responsibility, i.e., the physician introducing the concept of donation to the family and suggesting they speak further with another individual. Hospital staff who might help are the organ donation officer, nurse, chaplain or social worker.

The person designated must be sensitive to the family's grief, patient, skilled in interpersonal communication and aware of the family dynamics and the socio-economic, religious and ethnic background.

In any case, one person should be the primary contact. To avoid any perception of a 'conflict of interest', no person involved with the potential transplant recipient should seek the family's consent to donation.

4.2 Timing

If the family understands that death is pending, the concept of donation may be introduced before brain death is diagnosed. Endorsement/consent is sought only after the criteria of brain death have been met.

The family's decision about donation is influenced by its ability to understand and accept the concept of brain death. Brain death must be explained thoroughly before the family is asked to decide.

4.3 Information To Convey

In addition to information about the diagnosis of death the following should be reviewed carefully with the family: (i) the concepts of organ and tissue donation and transplantation; (ii) the donation process; (iii) the time required; (iv) the financial obligation of the provincial health care system for any transportation of the donor body for organ removal; (v) the family's responsibilities (financial and other) for burial; (vi) the meaning of the consent form; (vii) the confidentiality of the donor's, donor family's and recipient's identities and (viii) the practice of sending a letter of appreciation to the donor family including general information about the outcome of the donation.

Under no circumstances should the family be under pressure to consent. Assurance must be given that whatever their decision, it will be respected.

5. Donor Support

5.1 Objectives of Donor Support

The objective of support of perfusible organ donors is to maintain stable cardiac and respiratory function until the organs are removed. This requires intensive medical and nursing care. Timely identification and management of changes in vital signs and urinary output are required.

The objective of donor support in eye donation is limited to keeping the eyes moist until removal.

5.2 Responsibility for Donor Support

Where staffing permits it is preferable to designate an organ donation team to provide donor support. This decreases the emotional strain on I.C.U. staff

caused by the transition from preserving life and facilitates pre-operative assessments and arrangements. However, staff who wish to extend their "caring role" to include donor support should be allowed to continue.

5.3 The Elements of Donor Support

A donor hospital should consult with the regional transplant program about protocols for donor support.

Donor support usually occurs in an intensive care unit to facilitate monitoring of cardiovascular and pulmonary function and fluid and electrolyte balance. Regardless of the organs to be removed, certain tests will be required routinely. Blood and tissue samples must be taken and sent to a tissue-typing laboratory (in-house or other designated laboratory). Additional samples may be sent with the donor organ or donor body to the transplant centre. Special tests may be required to determine the suitability of specific organs for donation.

During the period of donor support, endorsement/consent is obtained from the family, recipient selection is made, transportation of organs or the donor body is arranged and operating rooms are prepared.

The following represent the key factors in donor support:

- appropriate hydration;
- maintenance of a systolic blood pressure of more than 90mm Hg. (Hypotension is the most frequent problem in donors);
- maintenance of an acceptable electrolyte balance;
- maintenance of sufficient urine output;
- maintenance of acceptable blood gas levels;

- maintenance of a near normal body temperature.

If cardiac arrest occurs, circulation must be restored immediately. Donor surgery should then be performed as soon as possible.

6. Organ Removal

For perfusible organs, the donor surgery must take place in a well-equipped, sterile operating room. Bone, skin and eye removal may be carried out in any environment in which a sterile technique can be maintained. In the case of tissue removal for transplant purposes the organ donor support system should be disconnected before removal begins.

Kidneys are usually removed by local surgeons who are experienced in kidney removal for transplantation and have staff privileges at the hospital or, less often, by an itinerant retrieval team from the regional transplant centre. For multi-organ retrieval, one or more itinerant retrieval teams from in-province, out-of-province or out-of-country may travel to the donor hospital. This adds to the complexity of the organ retrieval process and demands additional coordination in arranging for (i) the arrival and departure of one or more retrieval teams; (ii) the granting of staff privileges to retrieval team members; (iii) operating room schedules and (iv) donor preparation. Heart/lung and lung donors are usually transferred and pancreas donors must be transferred to the receiving transplant centre.

Where the same retrieval team comes frequently to a donor hospital a more permanent arrangement for granting privileges may be desirable. In all cases the identity of retrieval team members should be verified by the organ donation officer or designate before any operative procedure occurs.

The timing of the surgery will depend on the availability of an operating room, the stability of the donor and the arrival time of itinerant retrieval teams. As organ removal is usually urgent, the

same consideration should be given to booking surgery for it as to booking other emergency surgery. Operating time required varies with the number and types of organs removed. No surgery should occur until the diagnosis of brain death, the pronouncement of death, signed endorsement/consent of the family and permission of the coroner/medical examiner if required, have been recorded on the chart.

Staff in donor hospitals will assist itinerant retrieval teams. In most cases, itinerant teams include a perfusionist and bring the necessary preservation solutions, equipment and materials for organ perfusion and storage. If not, or if retrieval is by a local team, donor hospitals should ensure appropriate staff, supplies and equipment are available for that purpose.

Anaesthesiology staff must be able to provide pulmonary, hemodynamic and pharmacological management intra-operatively.

Eye, bone and skin removal should be performed as soon as possible but no later than 12 hours after death.

7. Organ and Tissue Preservation

7.1 Perfusible Organs

The key principles of perfusible organ preservation for immediate transplantation or transportation to another facility for transplantation are:

(a) to preserve the function of organs in the donor by effective donor support;

(b) to keep the warm ischemic time[13] as short as possible;

(c) to obtain core cooling with an appropriate flush solution after organ removal.

The current practice in Canada is to utilize simple, hypothermic, static storage systems for renal and extra-renal preservation. The alternative preservation method, pulsatile perfusion by a machine using a fluid with some proteins and an extra-cellular-fluid-like electrolyte solution, is more expensive and complex. Whether it contributes significantly to improved graft survival remains contentious.

Current preservation techniques limit time available for recipient selection and preparation and for organ transportation. Permissible times without blood circulation are:

Kidney	-	up to 72 hours
Liver	-	up to 8 hours
Heart		up to 5 hours
Lung	-	up to 4 hours
Heart/Lung	-	up to 4 hours
Pancreas	-	currently cannot be preserved as a whole organ.

7.2 Tissues

Eyes should be supported on a piece of moistened guaze and then placed in a sterile glass bottle. The bottle should then be packed in ice. If not used locally, the eyes should be transported expeditiously to the regional eye bank using the container provided by the bank. The hospital organ

13. The ischemic time is the time elapsed between the clamping of the donor blood supply and the restoration of blood supply in the new host. This time can be divided into the cold ischemic time, when the graft is preserved at about 4° to 7°C, and the warm ischemic time, when the graft is at or near body temperature.

donation officer should communicate with the eye bank regarding transportation arrangements. Eyes may be stored under suitable conditions for up to 48 hours before transplantation.

Skin should be placed in a short-term nutrient solution and refrigerated for immediate local use. Otherwise, it should be placed in the solution, packed in ice and transported to the regional skin bank.

Bones to be used as fresh allografts should be placed in a sterile container in an antibiotic solution and refrigerated. They may be stored in this manner for up to 48 hours following removal. Bones or segments not to be used as fresh allografts should be immediately packaged in an antibiotic solution, packed in ice and transported immediately to the regional bone bank.

For skin and bone donations, the hospital organ donation officer should consult with the regional transplant programs or relevant banks regarding preservation techniques and equipment and transportation arrangements.

8. Organ Sharing and Distribution

Patients accepted as candidates for transplantation are registered on waiting lists maintained by regional transplant or eye bank coordinators until appropriate organs or tissues become available.

Logistical considerations in organ and tissue distribution are the:

- ability to notify potential recipients;
- time required by recipients to travel to transplant centres;
- time required to prepare recipients for surgery;
- optimal preservation times for the organs or tissues to be transplanted.

Organs and tissues are exchanged between transplant centres within and outside provinces. When suitable recipients are not located in Canada, centres in the United States and elsewhere may be contacted. Arrangements for customs and immigration clearance are made by provincial transplant programs.

ORGAN AND TISSUE RETRIEVAL PROGRAMS IN CANADA
PROVINCIAL AND REGIONAL

ALBERTA

Human Organ Procurement and Exchange Program

Southern Alberta	Foothills Provincial General Hospital 1403 - 29th Street Northwest CALGARY, Alberta T2N 2T9 403-283-2243
Northern Alberta	University of Alberta Hospitals 112th Street and 83rd Avenue EDMONTON, Alberta T6G 2B7 403-432-1970

Lion's Eye Bank

Northern Division	c/o CNIB Offices 12010 Jasper Avenue EDMONTON, Alberta T5K OP3 403-482-4988
Southern Division	c/o Rockyview General Hospital 7007 - 14 Street Southwest CALGARY, Alberta T2V 1P9 403-259-7606

BRITISH COLUMBIA

Pacific Organ Retrieval for Transplantation	Vancouver General Hospital 855 - 12th Avenue VANCOUVER, B.C. V5Z 1M9 604-875-4665
British Columbia Eye Bank	2550 Willow Street VANCOUVER, B.C. V5Z 3N9 604-875-4555

MANITOBA

Manitoba Transplant Program	Health Sciences Centre 700 William Avenue WINNIPEG, Manitoba R3E OZ3 204-787-2071 ext. 505
Lion's Eye Bank (Manitoba and Northwestern Ontario)	700 William Avenue WINNIPEG, Manitoba R3E OZ3 204-787-3443

NEW BRUNSWICK

Organ Procurement for Transplantation, New Brunswick (Organ and Tissue Donation)	Saint John Regional Hospital SAINT JOHN, New Brunswick E2L 4L2 506-648-6848

NEWFOUNDLAND

Organ Procurement and Exchange Program (Organ and Tissue Donation)	Health Sciences Complex ST. JOHN'S, Newfoundland A1B 3V6 709-737-6600

NORTHWEST TERRITORIES

See Alberta and British Columbia (Dependent on relative proximity of donor to Alberta or British Columbia transplant centre).

NOVA SCOTIA

Maritime Organ Retrieval and Exchange Program	Victoria General Hospital HALIFAX, Nova Scotia B3H 2Y9 902-428-5504
Canadian National Institute for the Blind	6136 Alman Street HALIFAX, Nova Scotia B3G 2Y9 902-453-1480

ONTARIO

Multiple Organ Retrieval and Exchange Program	200 Elizabeth Street TORONTO, Ontario M5C 2G4 1-800-387-M.O.R.E. (Toll Free) 416-595-3587
Eye Bank of Canada (Ontario Division)	1 Spadina Crescent TORONTO, Ontario M5S 2J5 416-978-2637

PRINCE EDWARD ISLAND

See Nova Scotia

QUEBEC

Métro Transplantation	1560 Sherbrooke Street East MONTREAL, Québec H2L 4K8 514-876-6768

La Banque D'Yeux Nationale Inc.	2705 Boulevard Laurier SAINTE-FOY, Québec G1V 4G2 418-654-2702
La Banque d'yeux du Québec	5689 Boulevard Rosemont MONTREAL, Québec H1T 2H1 514-256-2681

SASKATCHEWAN

Lion's Eye Bank of Saskatchewan	c/o Eye Department University Hospital SASKATOON, Saskatchewan S7N OXO 306-966-1002
Renal Transplant Program University Hospital Saskatoon (For kidney donation only. May assist in referring donor hospitals in the case of other organs to programs outside the province)	University Hospital SASKATOON, Saskatchewan S7N 0X0 306-966-7985

YUKON

See Alberta and British Columbia (Dependent on relative proximity of donor to Alberta or British Columbia transplant centre).

SAMPLE CHECKLIST OF ACTIVITIES IN THE ORGAN AND TISSUE DONATION PROCESS[1]

PATIENT'S FAMILY ADVISED OF PROGNOSIS

(a) Family kept informed of patient's condition

PATIENT'S STATUS ASCERTAINED

(a) Police/ambulance driver asked about evidence of signed consent and/or patient's personal effects searched for signed consent (if patient has been admitted through Emergency).

PATIENT ASSESSED AS POTENTIAL DONOR

(a) Patient assessed for suitability according to donor criteria.

CONCEPT OF ORGAN DONATION INTRODUCED TO FAMILY

(a) Concept of organ donation introduced to family when appropriate depending on patient's condition and the family's ability to cope with impending death.

BRAIN DEATH DIAGNOSED

(a) Two confirmations of brain death documented in patient's chart.

(b) Time of death recorded.

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1. Many of these steps overlap or are carried out simultaneously. Their order may vary.

DONOR SUPPORT BEGUN

(a) Adequate respiration and circulation maintained.

(b) Body temperature maintained at near normal level.

(c) Blood and urine investigations conducted as prescribed by regional transplant program.

(d) Tests conducted to determine suitability of organs and tissues as prescribed by regional transplant programs.

HOSPITAL ORGAN DONATION OFFICER CONSULTED

(a) Officer consulted about donor support protocols, possible problems in donor support, family reactions to the patient's prognosis and suitability of organs and tissues for transplantation.

HOSPITAL ORGAN DONATION OFFICER AND REGIONAL TRANSPLANT PROGRAMS EXCHANGE INFORMATION

(a) Regional transplant programs consulted about suitability of organs and tissues for transplantation.

(b) Information exchanged on recipient selection, organ and tissue preservation and arrival of itinerant retrieval teams, if necessary.

(c) Arrangements made for transportation of organs, tissues or donor to transplant centre.

FAMILY APPROACHED ABOUT DONATION

(a) Family informed of donor's wish if indicated on the driver's licence/donor card and endorsement of consent sought.

(b) In absence of signed consent by donor, family asked for consent to donation.

(c) Consent form signed by appropriate family member and placed on donor's chart.

(d) Refusal of consent by family recorded in chart.

CORONER/MEDICAL EXAMINER NOTIFIED, IF APPROPRIATE

(a) Coroner/medical examiner notified and his/her permission obtained for organ removal and authorization documented in donor's chart.

TISSUE TYPING AND OTHER LAB TESTS DONE

(a) Samples of donor's blood obtained and transferred to tissue typing laboratory (in-house or regional laboratory as appropriate).

(b) Results conveyed to regional transplant programs.

ORGANS AND TISSUES REMOVED

(a) Operating room booked and surgeons, anaesthetists, operating room and recovery room staff confirmed. (Usually these arrangements have begun as soon as family endorsement of/consent for donation is obtained).

(b) Donor body transferred to other centre, if necessary.

(c) Samples of donor's spleen and lymph nodes obtained and transferred to tissue typing laboratory (in-house or regional laboratory as appropriate).

(d) For organs and tissues removed in an operating room, times recorded in donor's chart when body brought into operating room, incision made, removal completed and respirator turned off.

(e) For tissues (e.g. bone, skin or eyes) not removed in the operating room, body transferred to a sterile environment and tissues removed.

ORGANS TRANSPORTED/TRANSPLANTED

(a) Organs and tissues preserved and packaged for transportation to transplant centre(s).

(b) Body prepared for release to undertaker and family notified.

RECORD OF DONATION ACTIVITIES COMPLETED

(a) Record of donation process, (e.g. donor assessment, approach to family and outcome) in patient's chart completed by physician.

ANNEX III

ITEMS FOR INCLUSION IN A POLICY/PROCEDURES MANUAL ON THE ORGAN AND TISSUE DONATION PROCESS

The following outline of policies and procedures is offered as a guide to the development of the comprehensive set of policies and procedures required for an efficient and effective donation program.

Some of these policies/procedures may have been developed already for other purposes. However, special consideration should be given to them in the context of the donation program.

I. DEFINING THE ORGAN DONATION PROGRAM

- Philosophy, role and objectives of the program
- Extent and type of participation based on the audit of deaths to determine potential types and numbers of donations
- Services provided

II. ORGANIZATION OF SERVICES

- Governing board responsibility
- Relationship to administration and medical staff
- Program management:

  (i) Responsibilities of staff
  - Medical staff
  - Nursing staff
  - Hospital organ donation officer
  - Regional transplant co-ordinator
  - Other professional staff
  - Support staff

(ii) Committees
- Membership (defined by discipline and number)
- Terms of reference
- Provision for consultation with appropriate staff members
- Schedules for formal meetings

III. MEDICAL CARE AND RESPONSIBILITIES

- Identification of potential donors
- Identification and role of physicians for diagnosis of brain death
- Referral of potential donors to hospital donation officer/regional coordinators
- Notification of donors' attending or family physicians
- Designation of physicians responsible for donor support and organ and tissue removal
- Approaching donor families for endorsement/consent
- Determination of essential investigations and tests
- Transfer of donor to another centre
- Removal of organs and tissues
- Transportation of organs and tissues to transplant centre or, in the case of bone, skin and eye, to the appropriate bank
- Coverage for "off-hour" procedures

IV. NURSING CARE AND RESPONSIBILITIES

- Identification of potential donors
- Designation of key nursing staff and responsibilities for donor referral and support and organ and tissue removal

V. OTHER STAFF - ROLES AND RESPONSIBILITIES

- Health records
- Admitting department
- Hospital organ donation officer/transplant coordinator
- Social services - staff and/or community

- Chaplaincy services - staff and/or community
- Perfusionist
- Laboratory

VI. LEGAL CONSIDERATIONS

- Notification of coroner/medical examiner and recording of his/her consent for organ and tissue removal and/or autopsy
- Diagnosis of brain death
- Recording of donor family's endorsement/consent
- Privacy of organ donor and transplant recipient

VII. QUALITY ASSURANCE

- Review of practice standards
- Program evaluation
- Post-mortem audits to determine discrepancies between numbers of potential and actual donors
- Audits of donor cases
- Statistical records

VIII. OTHER

- Routine assessment of appropriate patients as potential donors
- Recorded consideration
- Granting of privileges to itinerant retrieval teams
- Staff training and continuing education
- Public relations
- Public education/community liaison
- Data collection and research
- Financial responsibilities and billing procedures
- Relationships with regional organ and tissue transplant programs

ANNEX IV

PROGRAM EVALUATION AND QUALITY ASSURANCE PARAMETERS AND PROCEDURES

Program evaluation for organ and tissue donation should deal with three things: organization, procedures and outcomes. Organizational evaluation looks at the systems in place for donation, including provincial, regional and institutional resources. The structure of the organization, its policies, procedures, communication channels, staff resources, training programs, and other prerequisites are reviewed in light of guidelines and other literature. If inadequacies are found, steps can be taken to improve the situation.

Procedural evaluation assesses whether appropriate written protocols and procedures are established and whether these are followed. Procedures which are out of date or difficult to follow are improved.

Outcome evaluation is concerned with the results of the entire exercise.

Anecdotal information on problems found in specific cases also may be useful as part of institutional or regional reviews. A random "case audit" may also be considered in addition to statistical reviews.

Program evaluation differs from quality assurance. Program evaluation emphasizes an overall perspective - the organization as a whole - and deals with policies and procedures which may not be directly related to day-to-day patient and family contacts. For instance, it can review efforts to publicize the donation program, gain the cooperation of the medical community or obtain the participation of area hospitals.

Quality assurance includes recording and reviewing performance in each case. Therefore, resources are

required to ensure that adequate records are kept and periodic audits undertaken. The audits should be based on individual record reviews and on statistics of services provided. For example, a review of patient records could be done to assess the elapsed time for each step in the process and determine if there are any significant delays that could be eliminated.

To achieve an objective, comprehensive and systematic evaluation, all indicators to be reviewed should be established beforehand. Where possible, parameters should be defined for each indicator.

It is preferable to collect statistics in standard format and to include:

- the number of potential donors by type of organ and tissue;
- the number of cases where a donation was sought and by whom;
- the number of endorsements of/consents to donation obtained;
- the numbers and types of organ and tissue donations;
- the numbers and types of organs and tissues successfully retrieved;
- the numbers and types of organs and tissues successfully transplanted.

Audits should be undertaken regularly in accordance with the hospital accreditation program. Consideration should be given to the potential for integrated audits encompassing the roles of all participants in the organ and tissue donation network.

Both quality assurance and program evaluation try to answer the question: How can we do the job better? To this end their focus should be flexible.

Persons charged with reviewing programs should be inventive. The evaluation or audit process itself should develop specific recommendations and, even it could be audited on its production of these. Recommendations and supporting evidence should be presented to the hospital administration and, where necessary, to the board of trustees for consideration and action.

LEGAL CONSIDERATIONS

The Human Tissue Gift Acts[1,2] apply to non-regenerative organs and tissues. Regenerative tissue is not included in the Acts, except in connection with the prohibition on sale of any body or body parts other than blood or a blood constituent, and in the provision for consent for the use of the body or body parts for certain purposes[3] after death. Gifts of skin and bone marrow by living persons are, therefore, regulated by the common law, which requires that donors have the capacity to understand the nature and consequences of the act involved. The protections afforded under the Human Tissue Gift Acts, including protection against civil liability, are not available where regenerative tissue is removed.

The Human Tissue Acts of Manitoba and New Brunswick, and the Human Tissue Ordinance of the Northwest Territories are older forms of legislation which do not provide for donations from living donors. Nevertheless, such donations follow generally approved medical practice and are probably legal at common law, despite the absence of direct Canadian authority on the question.

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1. Provinces and territories which have Human Tissue Gift Acts are Alberta, British Columbia, Newfoundland, Nova Scotia, Ontario, Prince Edward Island, Saskatchewan and the Yukon.

2. See also "Note on the Québec Civil Code", page 58.

3. These are therapeutic purposes, medical education or scientific research.

Gifts From Living Donors

Only the donors themselves may consent to the removal of their organs for transplant purposes. The donor must have attained the age of majority, be mentally competent to consent, and be able to make a free and informed decision. The consent must be in writing and signed by the donor.

Gifts To Be Used After The Donor's Death

The donor must have attained the age of majority and may consent in a writing signed by him; or he may give an oral consent in the presence of at least two witnesses during his last illness. Except where there is reason to believe that the consent to a gift to be used after death was subsequently withdrawn, the consent is authority for removal and use of the organ. However, the usual hospital practice is to ensure that the donor's family agrees with the donation.

If the donor has not given consent to the removal of an organ after death, consent may be given by any of the following persons in descending order of priority provided they have no reason to believe the donor would have objected:

- spouse
- child who has reached the age of majority
- either parent
- any brother or sister who has reached the age of majority
- any other next-of-kin who has reached the age of majority
- person lawfully in possession of the body (excluding the administrative head of the hospital, the coroner or medical examiner, the Public Trustee or similar official, an embalmer or funeral director, and the superintendent of a crematorium).

The consent may be given by the above persons either in a signed writing; or orally in the presence of at least two witnesses; or by a telegraphic, recorded telephonic, or other recorded message.

Donor Cards

Signed donor cards are often carried on the person of those wishing to donate organs to be used after death and may be attached to the driver's licence. Consent may be given in signed wills, whether or not the will is valid. However, as a practical matter, wills are not useful instruments for recording such consent.

Note On The Ouebec Civil Code

The Civil Code provides that adults may consent in writing to be living donors and a minor "capable of discernment" may consent in writing to be a living donor as long as this is done "with the authorization of a judge of the Superior Court and with the consent in writing of the person having paternal authority, provided that no serious risk to his health results therefrom."

In the absence of instructions by a deceased, the Civil Code permits the physician to remove a part of the remains if he obtains the consent of the consort or nearest relative of the deceased. The Civil Code also provides that "This consent is not necessary when two physicians attest in writing to the impossibility of obtaining it in due time, the urgency of the operation, and the serious hope of saving a human life."

Role of the Coroner Or Medical Examiner

Where there is reason to believe that there were unusual circumstances surrounding a patient's death the body cannot be interfered with in any way until the coroner or medical examiner gives his consent. Thus in cases involving accidents or other violence or in sudden and unexpected deaths, the coroner's consent for the removal of organs or tissues is required. Even though death has not yet occurred, the Human Tissue Gift Acts authorize a coroner to

approve organ/tissue removal after the donor's death where consent has been obtained to a transplant donation after death and death is imminent.

Legislation in most provinces (the exceptions are British Columbia, Quebec, and the two territories) authorizes the taking of pituitary glands during a coroner's or medical examiner's postmortem (in some cases during any authorized postmortem) provided there is no reason to believe there was an objection from the deceased or his relatives. This 'presumed consent' approach is also taken by Saskatchewan legislation which authorizes the taking of the corneo-scleral button during a coroner's postmortem. In the latter case, a recipient for corneal transplant must be immediately available.

Determination of Death

In the case of perfusible, non-regenerative organs, the Human Tissue Gift Acts require that, for the purposes of a postmortem transplant, the fact of death be determined by at least two physicians in accordance with accepted medical practice. A physician who has had any association with the proposed recipient which might influence his judgment cannot take any part in determining the fact of death of the donor. A physician who takes any part in the determination of the fact of death of the donor cannot participate in any way in the transplant procedures. These provisions are intended to avoid any conflict of interest on the part of the physician and to protect the interests of the donor.

The Quebec Civil Code requires that before the physician takes a body part from a dead donor, the death of the donor be ascertained by two physicians who do not participate in any way in the removal or in the transplantation.

Brain Death

The Human Tissue Gift Acts' provisions on the determination of death are directed to the process of actually determining death as opposed to defining

it. Manitoba is the only jurisdiction in Canada with a legislative definition of death. The Manitoba Vital Statistics Act includes the following definition: "For all purposes within the legislative competence of the Legislature of Manitoba, the death of a person takes place at the time at which irreversible cessation of all that person's brain function occurs."

Accepted medical criteria for the determination of death include permanent cardiac arrest as well as criteria which indicate brain death. The donor is declared dead when the appropriate medical criteria for the determination of death have been met.

Transportation Of Brain Dead Donors

Arrangements should be made with transportation services under a policy which recognizes the status of the donor as a person declared "brain dead" but supported on a donor support system to ensure respiration and heart beat.

Disposition of Donor Body

Arrangements should be made with the donor's family or in accordance with acceptable hospital practice.

International Transportation of Organs and Brain Dead Donors

Revenue Canada (Customs) departmental policy is to deal with this in an expeditious manner. There should not be any customs-related problems which would delay the return of a body after organ/tissue removal. A death certificate indicating the cause of death should accompany bodies entering Canada for interment.

Physician Licensing And Hospital Privileges

Policies should be established for licensing out-of-province and out-of-country physicians for organ

retrieval. Arrangements should also be made to provide temporary hospital privileges for such persons.

Confidentiality

Most Human Tissue Gift Acts prohibit disclosing information which could identify organ/tissue donors and recipients, except where the information disclosed pertains only to the person giving the information. The Saskatchewan Act permits an authorized person to disclose information that would identify the donor. The British Columbia Act permits the publication of the donor's as well as the recipient's identity where written consents have been obtained; if the recipient is under the age of majority (19 in British Columbia), his parent or guardian must consent; if the donor is dead or under the age of majority, consent must be obtained from any one of the designated persons.

APPENDIX I

(See page 76)

HUMAN TISSUE GIFT ACT

(Revised 1971)

Interpretation

1. In this Act,

(a) "consent" means a consent given under this Act;

(b) "physician" means a person (to be adapted to refer to licensing or registration under provincial Medical Act);

(c) "tissue" includes an organ, but does not include any skin, bone, blood, blood constituent or other tissue that is replaceable by natural processes of repair;

(d) "transplant" as a noun means the removal of tissue from a human body, whether living or dead, and its implantation in a living human body, and in its other forms it has corresponding meanings;

(e) "writing" for the purposes of Part II includes a will and any other testamentary instrument whether or not probate has been applied for or granted and whether or not the will or other testamentary instrument is valid.

PART I–*INTER VIVOS* GIFTS FOR TRANSPLANTS

Transplants under Act are lawful

2. A transplant from one living human body to another living human body may be done in accordance with this Act, but not otherwise.

Consent for transplant

3. (1) Any person who has attained the age of majority, is mentally competent to consent, and is able to make a free and informed decision may in a writing signed by him consent to the removal forthwith from his body of the tissue specified in the consent and its implantation in the body of another living person.

Consent for person under age, etc.

(2) Notwithstanding subsection 1, a consent given thereunder by a person who had not attained the age of majority, was not mentally competent to consent, or was not able to make a free and informed decision is valid for the purposes of this Act if the person who acted upon it had no reason to believe that the person who gave it had not attained the age of majority, was not mentally

competent to consent, and was not able to make afree and informed decision, as the case may be.

(3) A consent given under this section is full authority for any physician. Consent is full authority to proceed

(a) to make any examination necessary to assure medical acceptability of the tissue specified therein; and

(b) to remove forthwith such tissue from the body of the person who gave the consent.

(4) If for any reason the tissue specified in the consent is not removed in the circumstances to which the consent relates, the consent is void. Stale consent void

PART II–*POST MORTEM* GIFTS FOR TRANSPLANTS AND OTHER USES

4. (1) Any person who has attained the age of majority may consent. Consent by person for use of his body after death

(a) in a writing signed by him at any time; or

(b) orally in the presence of at least two witnesses during his last illness,

that his body or the part or parts thereof specified in the consent be used after his death for therapeutic purposes, medical education or scientific research.

(2) Notwithstanding subsection 1, a consent given by a person who had not attained the age of majority is valid for the purposes of this Act if the person who acted upon it had no reason to believe that the person who gave it had not attained the age of majority. Where donor under age

(3) Upon the death of a person who has given a consent under this section, the consent is binding and is full authority for the use of the body or the removal and use of the specified part or parts for the purpose specified, except that no person shall act upon a consent given under this section if he has reason to believe that it was subsequently withdrawn. Consent is full authority, exception

5. (1) Where a person of any age who has not given a consent under section 4 dies, or in the opinion of a physician is incapable of giving a consent by reason of injury or disease and his death is imminent, Consent by spouse, etc., for use of body after death

(a) his spouse of any age; or

(b) if none or if his spouse is not readily available, any one of his children who has attained the age of majority; or

(c) if none or if none is readily available, either of his parents; or

(d) if none or if neither is readily available, any one of his brothers or sisters who has attained the age of majority; or

(e) if none or if none is readily available, any other of his next of kin who has attained the age of majority; or

(f) if none or if none is readily available, the person lawfully in possession of the body other than, where he died in hospital, the administrative head of the hospital,

may consent,

(g) in a writing signed by the spouse, relative or other person; or

(h) orally by the spouse, relative or other person in the presence of at least two witnesses; or

(i) by the telegraphic, recorded telephonic, or other recorded message of the spouse, relative or other person,

to the body or the part or parts thereof specified in the consent being used after death for therapeutic purposes, medical education or scientific research.

Prohibition

(2) No person shall give a consent under this section if he has reason to believe that the person who died or whose death is imminent would have objected thereto.

Consent is full authority, exceptions

(3) Upon the death of a person in respect of whom a consent was given under this section the consent is binding and is, subject to section 6, full authority for the use of the body or for the removal and use of the specified part or parts for the purpose specified except that no person shall act on a consent given under this section if he has actual knowledge of an objection thereto by the person in respect of whom the consent was given or by a person of the same or closer relationship to the person in respect of whom the consent was given than the person who gave the consent.

Person lawfully in possession of body, exceptions

(4) In subsection 1, "person lawfully in possession of the body" does not include,

(a) the supervising coroner or a coroner in possession of the body for the purposes of *The Coroners Act* (to be adapted to provincial requirements);

(b) the Public Trustee in possession of the body for the purpose of its burial under *The Crown Administration of Estates Act* (to be adapted to refer to provincial provisions for administration of estates by the Crown);

(c) an embalmer or funeral director in possession of the body for the purpose of its burial, cremation or other disposition; or

(d) the superinendent of a crematorium in possession of the body for the purpose of its cremation.

Coroner's direction

6. Where in the opinion of a physician, the death of a person is imminent by reason of injury or disease and the physician has reason to believe that section ..... of *The Coroners Act* (to be adapted to refer to provincial provisions making the death a coroner's case) may apply when death does occur and a consent under this Part has been obtained for a post-mortem transplant of tissue from the body, a coroner having jurisdiction, notwithstanding that death has not yet occurred, may give such directions as he thinks proper respecting the removal of such tissue after the death of the person, and every such direction has the same force and effect as if it had been made after death under section ..... of *The Coroners Act* (to be adapted to refer to provincial provision empowering coroner to permit interference with body after death).

Determination of death

7. (1) For the purposes of a post-mortem transplant, the fact of death shall be determined by at least two physicians in accordance with accepted medical practice.

Prohibition

(2) No physician who has had any association with the proposed recipient that might influence his judgment shall take any part in the determination of the fact of death of the donor.

Idem

(3) No physician who took any part in the determination of the fact of death of the donor shall participate in any way in the transplant procedures.

Exception

(4) Nothing in this section in any way affects a physician in the removal of eyes for cornea transplants.

Where specified use fails

8. Where a gift under this Part cannot for any reason be used for any of the purposes specified in the consent, the subject matter

of the gift and the body to which it belongs shall be dealt with and disposed of as if no consent had been given.

PART III—GENERAL

Civil liability

9. No action or other proceeding for damages lies against any person for any act done in good faith and without negligence in the exercise or intended exercise of any authority conferred by this Act.

Sale, etc., of tissue prohibited

10. No person shall buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or part or parts thereof other than blood or a blood constituent, for therapeutic purposes, medical education or scientific research, and any such dealing is invalid as being contrary to public policy.

Disclosure of information

11. (1) Except where legally required, no person shall disclose or give to any other person any information or document whereby the identity of any person,

(a) who has given or refused to give a consent;

(b) with respect to whom a consent has been given; or

(c) into whose body tissue has been, is being or may be transplanted,

may become known publicly.

Exception

(2) Where the information or document disclosed or given pertains only to the person who disclosed or gave the information or document, subsection 1 does not apply.

Lawful dealings not affected, exception

12. Any dealing with a body or part or parts thereof that was lawful before this Act came into force shall, except as provided in this Act, continue to be lawful.

Offence

13. Every person who knowingly contravenes any provision of this Act is guilty of an offence and on summary conviction is liable to a fine of not more than $1,000 or to imprisonment for a term of not more than six months, or to both.

Application of *The Coroners Act*

14. Except as provided in section 6, nothing in this Act affects the operation of *The Coroners Act* (to be adapted to provincial requirements).

ANNEX VI

THE HOSPITAL ORGAN DONATION OFFICER - RESPONSIBILITIES

The extent of the officer's responsibilities will depend on the number of donors and may include:

- Conducting post-mortem audits;
- Providing or monitoring staff in-service education on organ and tissue donation and transplantation;
- Serving as a resource to hospital staff;
- Receiving donor referrals from physicians and nurses;
- Arranging for transfer of potential donors to secondary or tertiary care centres;
- Assisting with preparation and support of donors;
- Liaising with regional transplant programs on all organ and tissue donations e.g., arranging for evaluation, tissue typing and cross-matching of potential donors, approaching donor families about donation;
- Ensuring that diagnosis of brain death is recorded according to policy;
- Ensuring that the coroner/medical examiner is notified when necessary and that resulting decisions are recorded in the chart;
- Arranging for donor surgery including arranging for arrival and departure of, and hospital privileges for, itinerant retrieval teams;
- Assisting with removal of organs and tissues where necessary;

- Assisting with preparation and storage of organs and tissues;

- Arranging transportation of organs and tissues;

- Responding to requests for information and initiating community education programs in consultation with regional transplant and eye bank coordinators;

- Collecting data for own hospital and for regional transplant programs.

ANNEX VII

REGIONAL TRANSPLANT AND EYE BANK COORDINATORS - RESPONSIBILITIES RELATED TO THE ORGAN AND TISSUE DONATION PROCESS

In addition to those responsibilities of a hospital organ donation officer outlined in Annex VI, regional transplant and eye bank coordinators may:

- Provide guidance to area hospitals interested in establishing donor programs including advising in the development of policies and procedures and in-service education programs;

- Assist in the donation of organs and tissues (eye bank coordinators assist in the donation of eyes only);

- Give advice in borderline or difficult cases;

- Participate in the removal and transportation of organs/tissues (eye bank coordinators do not participate in the removal of eyes);

- Provide feedback to staff of donor hospitals and to donor families after donation;

- Undertake regional or provincial professional and public education activities including producing and distributing materials;

- Coordinate and/or participate in local, regional and national research efforts and data collection.

ANNEX VIII

GUIDELINES FOR THE DIAGNOSIS OF BRAIN DEATH*

Preamble. The development of techniques for the ventilatory and circulatory support of critically ill patients has created a need for new definitions of death. Although irreversible cessation of circulatory and respiratory functions acceptably defines death, irreversible cessation of brain function is also equivalent to death of the individual even though the heart continues to beat while the person is on a respirator (1). In 1968, following the publication of the "Harvard Criteria" (2) for the diagnosis of brain death, the Canadian Medical Association provided guidelines (3) that were subsequently revised (4, 5). In 1976, guidelines were published for the U.K. (6) and in 1981 revised guidelines were published in the Journal of the American Medical Association (7). The following set of guidelines was prepared by a subcommittee of the Canadian Congress of Neurological Sciences and has been approved by the memberships of the Canadian Neurological Society, the Canadian Neurosurgical Society, the Canadian Association for Child Neurology and the Canadian Society of Clinical Neurophysiologists.

The determination of brain death is a clinical decision that must be made by an experienced physician in accordance with accepted medical standards (7). Thus, the guidelines described below are based on current medical information and experience. As knowledge advances, it can be anticipated that further revisions will become necessary. Because of

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*. These guidelines were developed by the Canadian Congress of Neurological Sciences and endorsed by the Canadian Medical Association in 1986.

the major consequences of the diagnosis of brain death, consultation with other physicians experienced in the relevant clinical examinations and diagnostic procedures is usually advisable.

Guidelines. The clinical diagnosis of brain death can be made when all of the following criteria have been satisfied:

1. An etiology has been established that is capable of causing brain death and potentially reversible conditions have been excluded (see Comment 2, below).

2. The patient is in deep coma and shows no response within the cranial nerve distribution to stimulation of any part of the body. No movements such as cerebral seizures, dyskinetic movements, decorticate or decerebrate posturing arising from the brain are present (see 1a, below).

3. Brain-stem reflexes are absent (see 1b, below).

4. The patient is apneic when taken off the respirator for an appropriate period of time (see 1c, below).

5. The conditions listed above persist when the patient is reassessed after a suitable interval (see 2, below).

Comments. Although the purpose of this document is to state general principles and recommend guidelines rather than outline a set of rules, certain features of the guidelines merit more detailed explanations.

1. Cessation of Brain Function. The clinical absence of brain function is defined as: profound coma, apnea, and the absence of brain-stem reflexes.

a. Coma The patient should be observed for spontaneous behaviour and response to noxious stimuli. In particular, there should be no motor response within the cranial nerve distribution to stimuli applied to any body region. There should be no spontaneous or elicited movements (dyskinesias, decorticate or decerebrate posturing, epileptic seizures) arising from the brain. However, various spinal reflexes may persist in the state of brain death (8).

b. Brain-stem Reflexes. The pupillary light, corneal, vestibulo-ocular and pharyngeal reflexes must be absent. The pupils should be mid-size or larger and must be unreactive to light. Care should be taken that atropine or related drugs that could block the pupillary response to light have not been given to the patient. The vestibulo-ocular reflexes should be tested by doing caloric tests while the head is 30 degrees above the horizontal. In adults, a minimum of 120 ml of ice water should be used(9). Grimacing or any other motor response to pharyngeal or tracheal suctioning is incompatible with a diagnosis of brain death.

c. Apnea was originally defined as lack of respirations when the patient was disconnected from the respirator for three minutes. This failed to take into consideration whether an adequate $PaCO_2$ level was present to trigger respirations. The threshold for respiratory stimulation in comatose patients may be elevated to $PaCO_2$ levels as high as 50 - 55 mm Hg and many patients on respirators have low $PaCO_2$ levels which rise slowly (e.g. 2-3 mm Hg per minute) when the respirator is stopped (10). In patients who fulfill the other clinical criteria of brain death, the technique of apneic oxygenation, described below, is a safe way of testing respiratory activity (11).

If blood gas determinations are available, the $PaCO_2$ should be 40+/-5 mm Hg before testing for apnea begins. The respirator is then disconnected for 10 minutes while, to prevent

hypoxemia, 100% O_2 is delivered at 6 litres/minute through an endotracheal cannula. This should ensure an adequate rise in $PaCO_2$ to serve as a respiratory stimulant. If blood gas determinations are not available, an adequate test of brain-stem responsiveness to hypercarbia can be provided by ventilating the patient for 10 minutes with a 95% O_2-5% CO_2 mixture before the 10 minute period of apneic oxygenation (7). In patients with severe respiratory disease, it is advisable to obtain the opinion of a respiratory physician to determine the safety and validity of this test for apnea.

Testing for apnea without passive oxygenation is not recommended. In addition to its potential deleterious effects on the brain, the resultant hypoxemia can occasionally cause complex movements of the limbs and trunk, presumably due to spinal cord ischemia, that could be confused with reflex movements of cerebral origin (12).

2. Irreversibility: Cessation of brain function is determined to be irreversible when potentially reversible causes have been excluded and the changes are judged to be permanent. Drug intoxication (particularly barbiturates, sedatives, and hypnotics), treatable metabolic disorders, hypothermia (core temperature less than 32.2°C), shock and peripheral nerve, cranial nerve or muscle dysfunction due to disease or neuro-muscular blocking drugs must be excluded.

Re-evaluation is essential to ensure that the non-functioning state of the brain is persistent (13) and to reduce the possibility of observer error (6). Depending on the etiology, the interval between such examinations may be as short as 2 hours or as long as 24 hours; observation for at least 24 hours is usually recommended to confirm brain death due to anoxia-ischemia (e.g. post-cardiac arrest) (7). In situations where brain death is declared for purposes of organ transplantation, local regulations may stipulate specific intervals for reassessment.

Special Circumstances:

1. Infants and Children. Brain death has not been sufficiently well studied in neonates, infants and young children to determine if the clinical criteria listed above apply to the pediatric age groups. In one study, the presence of these criteria for three days was associated with brain death in all children studied (14). When clinical criteria alone are used to make the diagnosis of brain death in children, a longer period of observation than in adults may be required. Where facilities exist for the demonstration of absent cerebral blood flow by radionuclide scintigraphy or cerebral angiography these methods may allow a diagnosis of brain death to be made in the pediatric population in a shorter period of time.

2. Inability to Apply the Clinical Criteria. Some clinical situations such as uncertainty regarding etiology, inability to examine one or both eyes due to trauma, middle ear injuries, cranial neuropathies or severe pulmonary disease may preclude the valid application of the listed clinical criteria. In these circumstances, the only reliable means of confirming brain death is the absence of cerebral perfusion, determined by cerebral angiography or radionuclide scintigraphy.

Laboratory Tests:

Although brain death can be established reliably by clinical criteria alone (1,2,6,7,13), special tests can be used to support and, in some instances, to supplement the clinical diagnosis. The electroencephalogram (EEG) assesses cerebral cortical function. Electrocerebral inactivity is confirmatory evidence of brain death only if the full clinical criteria apply and established techniques (15) are followed to ensure proper sampling of cortical activity. Visual, auditory, and somatosensory evoked responses, or other tests may eventually prove to be useful but, at present, there are no

standard guidelines for their use in assessing patients with suspected brain death.

The absence of intracranial perfusion, demonstrable by cerebral angiography or radionuclide scintigraphy, is reliable evidence of brain death (16). The mean arterial pressure should be greater than 80 mm Hg when cerebral perfusion is assessed. If cerebral angiography or radionuclide scintigraphy is used to determine the absence of cerebral perfusion, the procedure should be performed by an appropriately qualified specialist.

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ANNEX IX

CRITERIA FOR ORGAN AND TISSUE DONATION

Note 1. Criteria may be slightly different in some centres. In cases of doubt consultation with the regional transplant programs is advised.

2. Further investigations - hematological, biochemical, radiological - specifically related to organ function may be required.

3. All donations may not satisfy the ideal criteria for selection. The risks of transplanting sub-optimal organs may be less than the risks for a particular recipient of deferring transplantation.

A. PERFUSIBLE ORGANS

Kidney

- Age: 1 - 70 years
- No history of pyelonephritis or other chronic renal disease
- No acute renal infection. Localized sepsis not involving the upper urinary tract and responding to treatment, is not a cause for exclusion.
- No history of diabetes or hypertension requiring drug treatment. Mild cases are considered.
- No consequences of previous injectable drug abuse (requires evaluation regarding nephrotoxicity and hepatitis)
- No recent injury or surgery of abdomen
- No prolonged hypotension
- Acceptable renal function as indicated by satisfactory blood pressure, urine output, urinalysis, serum electrolytes, creatinine, urea, glucose.

Note

Impaired kidney function due to prerenal factors (e.g. therapeutic dehydration and/or loss of vasoregulatory function associated with brain-stem

damage) does not disqualify a donor if early treatment with aggressive hydration results in improved renal perfusion as demonstrated by declining serum creatinine and urea. Also, elevated serum glucose levels alone (seen in patients receiving steroid therapy and dextrose infusion) are not necessarily a contra indication.

Heart

- Age: 1 - 40 years
- No history of congenital heart disorder or cardiac disease (infective, ischemic, valvular)
- No recent injury or surgery of abdomen.
- No prolonged cardiac arrest (Cardiac arrest may be acceptable if resuscitation is immediate with normal cardiopulmonary status and no cardiac injury.)
- Satisfactory blood pressure, ECG, chest x-ray.
- No intracardiac injections (in large doses or over a prolonged time).

Note

Bradycardia, tachycardia and hypertension secondary to acute brain stem compression do not contraindicate donation.

Tachycardia and hypotension due to hypovolaemia are not significant barriers to donation if aggressive hydration is instituted promptly to restore a normotensive blood pressure.

Heart-Lung

- Age: 1 - 40 years
- No history of cardiac or pulmonary disease
- No recent injury or surgery of abdomen
- No prolonged cardiac arrest (Cardiac arrest may be acceptable if resuscitation is immediate with normal cardiopulmonary status and no cardiac injury)
- No intracardiac injections (in large doses or over a prolonged time)

- Satisfactory blood pressure, chest examination, ECG, chest x-ray, arterial blood gases, sputum culture.

Liver

- Age: 6 months - 55 years
- No history of liver disease
- No history of diabetes mellitus
- No history of alcoholism
- No recent injury or surgery of abdomen
- No prolonged hypotension
- Satisfactory blood pressure, liver function tests - bilirubin, AST (SGOT), ALT (SGPT), PT/PTT.

Note

Localized sepsis not involving gastrointestinal tract and responding to treatment is not a cause for exclusion.

Elevated serum glucose levels alone (seen in patients receiving steroid therapy and dextrose infusion) are not necessarily a contraindication.

Lung

- Age: 1 - 50 years
- No history of pulmonary disease
- No recent injury or surgery of abdomen.
- No evidence of recent pulmonary embolism
- Satisfactory blood pressure, ECG, chest x-ray, sputum culture.

Pancreas

- Age: 1 - 60 years
- No history of pancreatitis
- No history of diabetes mellitus
- No history of alcoholism
- No recent injury or surgery of abdomen
- Satisfactory blood pressure, serum glucose, serum amylase.

Note

Elevated serum glucose levels alone (seen in patients receiving steroid therapy and dextrose infusion) are not necessarily a contraindication.

B. TISSUES

Eye

- Age: no limitation
- No chronic central nervous system disease
- No sepsis, no infectious hepatitis or other viral infection.

Bone and Joint

- Age: females aged 16-50; males aged 16-60
- Etiology of death known
- No history of metabolic bone disease
- No history of immune disease
- No long term therapy with high dosage steroids or any irradiation
- No past or present cancer
- No systemic infection.

Note

Trauma resulting in bone injury may not exclude donation.

Skin

- Age: no limitation
- No diffuse dermatitis. A history of previous disease of the skin may be acceptable.
- No long term antiobiotic therapy
- No drug abuse
- No past or present cancer
- No active infection or communicable disease.

Heart Valve

- Age: up to 60 years
- Evidence of normal valve function.

ANNEX X

SAMPLE FORM FOR RECORDING CONSIDERATION OF ORGAN/TISSUE DONATION

PATIENT IDENTIFICATION

To be completed by physician:

A. Date and time of death: _____

B. Diagnosis: _____

	YES	NO
1. Was patient assessed as a potential donor?		
2. If no, why not? _____ _____		
3. Did the patient meet "quick-screen" criteria for donation? (See chart overleaf)		
a) Perfusible organs: kidney, heart, liver, other (specify) _____		
b) Tissues: cornea, bone, skin, other (specify) _____		
c) Was hospital donation officer or regional transplant coordinator consulted?		
4. a) Was family approached for endorsement of/consent for donation? If no, why not? _____ _____		
b) Was endorsement/consent obtained?		
5. Were organs/tissues retrieved?		

_____
Physician's signature

_____
Date and time

ORGAN DONOR CRITERIA[1]

GENERAL CRITERIA FOR PERFUSIBLE ORGANS

Brain dead patients with NO

- Active infection
- History of hepatitis B or HIV (A.I.D.S.)
- Past/present malignancy outside CNS
- Current intravenous drug use
- Insulin dependent diabetes
- Severe chronic hypertension
- Disease or injury of organ considered for donation
- Recent injury or surgery of abdomen.

ORGAN SPECIFIC CRITERIA
(Quick-Screen)

	Kidney	Heart	Heart/ Lung	Liver	Lung	Pancreas
Age range	1-70	1-40	1-40	6 mos-55	1-50	1-60
Had had cardiac arrest but resuscitated	Prob. OK	Yes, if resuscitated immediately with normal cardiopulmonary status and no cardiac injury.		Prob. OK	Poss. OK	Prob. OK
Absence of active/previous disease of organ to be removed	Occasional exceptions	- - - - - - - - - MANDATORY - - - - - - - -				

GENERAL CRITERIA FOR TISSUES

Patients

- Dead on arrival or dying in hospital
- No - sepsis
  - extra-cranial malignancy
  - hepatitis or HIV (A.I.D.S.)
  - transmissible disease
- Perfusible organ donors
- Cause of death established

Heart beat and respiration are not requisites for tissue donation.

TISSUE SPECIFIC CRITERIA
(Quick-Screen)

	Eye	Bone	Skin
Age range	any age	female - 16-50 male - 16-60	any age
Absence of chronic CNS disease	Mandatory	Not mandatory	Not mandatory
Absence of recent/ previous disease of tissue to be removed	Mandatory	Mandatory	Usually not mandatory

1. Consult organ donation officer or regional transplant coordinator for more detailed criteria or in cases of doubt.

ANNEX XI

GUIDELINES FOR SPECIAL SERVICES IN HOSPITALS

The following guidelines have been prepared by the federal-provincial Subcommittee on Institutional Program Guidelines. These guidelines were requested by the Federal-Provincial Advisory Committee on Institutional and Medical Care Services. Some of the guidelines are updated versions of guidelines previously published by the Subcommittee.

Addiction Services in Hospitals
Adult Long Term Institutional Care
Adult Psychiatric Services Provided by General Hospitals
Breast Imaging Services: Mammography
Burn Unit
Cardiovascular Services in Hospitals
Child and Adolescent Psychiatric Services Provided by General Hospitals
Child and Youth Long Term Services in General Hospitals
Computed Tomography
Day Surgery Unit
Dental Care Units in Hospitals
Diabetic Day Care Unit
Diagnostic Imaging Services and Systems: An Overview
Diagnostic Ultrasound Facilities in Hospitals
Emergency Services in Hospitals
End-Stage Renal Disease Program
Geriatric Day Hospitals
Geriatric Unit in a Hospital
Intensive Care Unit
Magnetic Resonance Imaging
Nuclear Medicine in Hospitals
Organ and Tissue Donation Services in Hospitals
Palliative Care Services in Hospitals
Patient Hostel Unit
Perinatal Intensive Care Units in a Perinatal Care Network
Pre-Hospital Emergency Care Services

Pulmonary Function Laboratories
Rehabilitation Medicine Program
Respiratory Therapy Service
Reuse of Disposables: An Information Report
Spinal Cord Injury Program
Stroke Program
Vital Organ Transplant Centres